K060881

510(k) SUMMARY

As required by the Safe Medical Devices Act of 1990

DESCRIPTION OF THE APPLICANT DEVICE

MAY 16 2006

TRADE NAME: Multiple
COMMON NAME: Temporary Crown and Bridge Resin
CLASSIFICATION NAME: Temporary Crown and Bridge Resin (21 CFR 872.3770, Product code EBG)

Cosmedent TEMPORARY CROWN AND BRIDGE RESIN is a self-cure composite resin fabricated from difunctional acrylic monomers and silicaceous fillers. These materials have sufficient physical properties to function in the oral cavity for up to 90 days and have esthetic qualities that mimic natural tooth appearance.

The technological characteristics of the applicant device are essentially identical to the predicate device.

IDENTIFICATION OF THE LEGALLY MARKETED PREDICATE DEVICE

TRADE NAME: Luxatemp
COMMON NAME: Temporary Crown and Bridge Resin
CLASSIFICATION NAME: Temporary Crown and Bridge Resin (21 CFR 872.3770, Product code EBG)

SUBSTANTIAL EQUIVALENCE SUMMARY

EQUIVALENTS	Cosmedent TEMPORARY C & B Filling Material	LUXATEMP Temporary Filling Material
Intended Use	Similarities	
	Both products have identical intended uses as temporary crown and bridge filling materials	
Composition	Both products have substantially the same chemical composition. They are self-cure, silica filled, difunctional acrylic composites	
Physical properties	Both products have similar physical and mechanical properties as shown in Table 1 below	
How supplied and used	Both products are supplied as auto-mix systems. Preloaded syringes are mixed and dispensed in a hand-gun and the mixed material is either loaded into an impression and placed in the patient's mouth or the product is applied directly on the prepared tooth.	
Mechanical and Physical Properties	Cosmedent TEMPORARY C & B Filling Material	LUXATEMP Temporary Filling Material
Compressive strength	225 MPa	220 MPa
Flexural strength	82 MPa	92 MPa
Percent filler by weight	46	44
Radiopaque	Yes	Yes
	Differences	
Attachment pickup use	No	Yes

Submitted by: James L. Sandrik, PhD
Cosmedent, Inc.
401 N. Michigan Ave. Suite 2500
Chicago, IL 60611

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2006

James L. Sandrik, PhD
Director of Regulatory Affairs
Cosmedent, Incorporated
401 North Michigan Avenue, Suite 2500
Chicago, Illinois 60611

Re: K060881
Trade/Device Name: Temporary Crown and Bridge Resin
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: March 29, 2006
Received: March 31, 2006

Dear Dr. Sandrik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K060881

Device Name: MULTIPLE (TEMPORARY CROWN AND BRIDGE RESIN)

Indications For Use: Temporary CROWN AND BRIDGE Resin is indicated for use as a temporary restorative material for crown and bridge, inlay, and/or onlay restorations.

Prescription Use___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) K060881